DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Invitation to Manufacturers of Platforms for Nucleic Acid Amplification or Detection Suitable for Assay Development and Molecular Diagnostics for Detection of Agents that Cause Infectious Diseases

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is interested in obtaining information on available platforms for nucleic acid amplification or detection that meet criteria outlined below in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Manufacturers are asked to contact CDC at the address below by [INSERT DATE 45 DAYS AFTER PUBLICAITON IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Laura Hughes-Baker, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24-12, Atlanta, GA 30329-4027. Telephone: (404) 639-1402; Email: eocevent521@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: Nucleic acid amplification or detection is used in many diagnostic tests. Rapid and accurate results that can specifically detect small amounts of pathogen material are essential to identifying and tracking diseases. The recent pandemic has demonstrated the need for tests that can be used in public health laboratories across the United States and internationally.

Many CDC laboratories across the agency use a particular diagnostic platform for nucleic acid detection. Because this current platform will be retired in the future, CDC is interested in hearing from manufacturers regarding the availability of current and potential platforms that could support CDC's overall diagnostics and surveillance.

Criteria: Ideally, the replacement platform should:

- Be suitable for research, surveillance, or assay development, and in vitro diagnostic purposes;
- Have Food and Drug Administration (FDA) clearance for diagnostic use or a research platform capable of obtaining FDA clearance;

- Be compatible with a 96 well format;
- Be compatible with diagnostic, surveillance, or characterization tests targeting a variety of pathogens; and
- Have software that allows for flexibility in analysis.

Manufactures who may have a platform that meets these criteria should submit information to CDC at eocevent521@cdc.gov or the address provided in the **FOR FURTHER INFORMATION** section above.

All information submitted to CDC will be kept confidential as allowed by relevant federal law, including the Freedom of Information Act (5 U.S.C. 552) and the Trade Secrets Act (18 U.S.C. 1905).

Disclaimer and Important Notes

This notice is for planning purposes; it does not constitute a formal announcement for comprehensive applications. In accordance with Federal Acquisition Regulation 48 CFR 15.201(e), responses to this notice are not offers and cannot be accepted by the Government to form a binding award. CDC will not provide reimbursement for costs incurred in responding to this notice.

Dated: June 29, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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